

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in this application. The following amendments are made without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Applicants reserve the right to pursue the subject matter of the canceled claims in this or any other appropriate patent application.

Listing of Claims:

1. (Currently Amended) A method for treating an individual with non-small cell lung cancer stage IIIB locoregional, without malignant pleural effusion, comprising:

(a) selecting for treatment an individual who has non-small cell lung cancer stage IIIB locoregional, without malignant pleural effusion, and whose cancer has responded to treatment following completion of a first line standard chemotherapy and/or radiotherapy; and

(b) administering to that individual, a therapeutically effective amount of a MUC-1-based formulation, wherein said formulation comprises (i) a liposome comprising at least one polypeptide comprising an amino acid sequence selected from the group consisting of (1) amino acid sequences comprising at least five consecutive amino acids of any of SEQ ID NOs:1-8 and (2) amino acid sequences which are at least 80% identical to any of SEQ ID NOs:1-8, (ii) at least one adjuvant, and (iii) one or more additional liposomal lipids.

2. (Cancelled).

3. (Cancelled).

4. (Currently Amended) The method of claim 3-1, wherein the adjuvant is selected from the group consisting of lipid A, muramyl dipeptide, alum, and a cytokine.

5. (Original) The method of claim 4, wherein the lipid A is monophosphoryl lipid A or a synthetic mimic of lipid A.

6. (Cancelled).

7. (Previously Presented) The method of claim 1, further comprising a step (c) evaluating at least the cancer state or immunological activity of the treated individual.

8. (Cancelled).

9. (Previously Presented) The method of claim 7, wherein evaluating the treated individual comprises measuring an immune reaction in the treated individual.

10. (Original) The method of claim 9, wherein measuring the immune reaction in the treated individual comprises measuring a T-cell proliferation.

11. (Previously Presented) The method of claim 7, wherein evaluating the treated individual comprises determining at least one of: (a) tumor size, (b) tumor location, (c) nodal stage, (d) growth rate of the non-small cell lung cancer, (e) changes in the individual's lung cancer, or (f) changes in the individual's quality of life.

12. (Cancelled).

13. (Currently Amended) The method of claim 1, wherein the formulation comprises a BLP25 liposome vaccine, wherein the BLP25 liposome vaccine comprises (i) a MUC-1 peptide comprising the sequence of SEQ ID NOS: 1 or 2, (ii) an a lipid A adjuvant, and (iii) one or more additional liposomal lipids selected from the group consisting of dipalmitoyl phosphatidylcholine, cholesterol, and dimyristoyl phosphatidylglycerol.

14. (Original) The method of claim 13, wherein the BLP25 liposome vaccine is provided in a kit.

15. (Previously Presented) The method of claim 1, wherein the step of administering is by injection, aerosol, nasal delivery, or oral delivery, and wherein the injection is an intramuscular injection, a subcutaneous injection, intranodal, intratumoral, intraperitoneal, or an intradermal injection.

16. (Previously Presented) The method of claim 1, wherein the administration is for a period of time of at least about 2 weeks.

17. (Previously Presented) The method of claim 1, wherein the individual is treated with cyclophosphamide prior to (b).

18. (Currently Amended) A method for improving or maintaining the quality of life of an individual diagnosed with non-small cell lung cancer, comprising routinely administering to an individual diagnosed with non-small cell lung cancer stage IIIB locoregional, without malignant pleural effusion, and whose cancer has responded to treatment following completion of a first line standard chemotherapy and/or radiotherapy, a BLP25 liposome vaccine for a period of time, wherein the BLP25 liposome vaccine comprises (i) ~~comprises~~ a liposome comprising a polypeptide comprising an amino acid sequence selected from the group consisting (1) amino acid sequences comprising at least five consecutive amino acids of any of SEQ ID NOs:1-8 and (2) amino acid sequences which are at least 80% identical to any of SEQ ID NOs:1-8 (ii) an adjuvant, and (iii) one or more additional liposomal lipids, wherein said administration improves or maintains the quality of life of said individual.

19. (Cancelled).

20. (Currently Amended) The method of claim 18, further comprising calculating a combined score of the individual's physical well-being, functional well-being, and lung cancer ~~or prostate cancer~~ symptoms before, during, and after the period of time wherein the individual had been diagnosed with non-small cell lung cancer ~~or prostate cancer~~.

21. (Previously Presented) The method of claim 16, wherein the period of time is at least about 6 months.

22. (Previously Presented) The method of claim 13, wherein the dose of MUC-1 is about 1000 μ g and the dose of adjuvant is about 500 μ g.

23. (Previously Presented) The method of claim 13, wherein the amount of MUC-1 peptide is about 300 μ g.

24. (Cancelled).

25. (Original) The method of claim 24-13, wherein the amount of lipid A is about 150 μ g.

26. (Previously Presented) The method of claim 13, wherein the amount of additional liposomal lipids is about 15 mg.

27. (Previously Presented) The method of claim 13, wherein the MUC-1 peptide comprises the sequence depicted in SEQ ID NO: 1.

28. (Previously Presented) The method of claim 13, wherein the MUC-1 peptide comprises the sequence depicted in SEQ ID NO: 2.

29. (Original) The method of claim 27, wherein the MUC-1 peptide is lipidated.

30. (Cancelled).

31. (Previously Presented) The method of claim 1 wherein the polypeptide comprises at least five consecutive amino acids of any of SEQ ID NOs:1-8.

32. (Previously Presented) The method of claim 1 wherein the polypeptide comprises a sequence which is at least 80% identical in amino acid sequence to any of SEQ ID NOs:1-8.

33. (Previously Presented) The method of claim 1 wherein the polypeptide comprises at least five consecutive amino acids of any of SEQ ID NOs:1-8.

34. (Previously Presented) The method of claim 1 wherein the polypeptide comprises a sequence which differs from one of SEQ ID NOs:1-8, if at all, solely by one or more conservative substitution, a conservative substitution being

(c1) an amino acid exchange among alanine, valine, leucine and isoleucine,

(c2) an amino acid exchange between serine and threonine,

(c3) an amino acid exchange between aspartate and glutamate

(c4) an amino acid exchange between asparagine and glutamine,

(c5) an amino acid exchange between lysine and arginine, or

(c6) an amino acid exchange between phenylalanine and tyrosine.

35. (Previously Presented) The method of claim 1 wherein the polypeptide comprises a sequence which is at least 85% identical in amino acid sequence to any of SEQ ID NOs:1-8.

36. (Previously Presented) The method of claim 1 wherein the polypeptide comprises a sequence which is at least 90% identical in amino acid sequence to any of SEQ ID NOs:1-8.

37. (Previously Presented) The method of claim 1 wherein the polypeptide comprises a sequence which is at least 95% identical in amino acid sequence to any of SEQ ID NOs:1-8.

38. (Previously Presented) The method of claim 1 wherein said polypeptide comprises a sequence which differs from one of SEQ ID NOs:1-8, if at all, solely by 1-5 substitutions.

39. (Previously Presented) The method of claim 1 wherein said polypeptide comprises a sequence which differs from one of SEQ ID NOs:1-8, if at all, solely by replacement of one or more residues identifiable as non-critical residues by alanine-scanning mutagenesis.

40. (Previously Presented) The method of claim 18 wherein such effect on the quality of life is ascertainable from the change in FACT-L score for the individual after said administering.

41. (New) The method of claim 1, further comprising administering to the individual, a palliative radiotherapy and/or second line chemotherapy.

42. (New) The method of claim 41, wherein the palliative radiotherapy and/or second line chemotherapy is concomitant to administration to the MUC-1 formulation.

43. (New) The method of claim 41, wherein the palliative radiotherapy and/or second line chemotherapy is subsequent to administration to the MUC-1 formulation.

* * *